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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,252	07/08/2002	Tadanori Mayumi	MAYUMI=1	9722

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EXAMINER
NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
1632	9

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/070,252	Tadanori
Examiner	**Art Unit**
Dave Nguyen	1632

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 27, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

This instant application has been reassigned to another examiner.

Applicant's species restriction in the response filed January 2003 has been acknowledged. However, the species restriction has been withdrawn by the examiner.

Claims 1-13 are pending for examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 3, 7, 10, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 3, 7, 10, 12 are indefinite in the recitation of "the fusogenic capability derives from Sendai virus" because it is not apparent as to how a functional limitation which recites "fusogenic capability" of a liposome can be derived from a Sendai virus. It is not apparent how a biological activity of an structural entity can be extracted from another distinctly structural entity. Should applicant intend to claim that the liposome as claimed incorporate a Sendai virus so as to exhibit a fusogenic capability, the claim should be amended to reflect applicant's intention. Note that the phrase "from Sendai virus" lacks the article "a" between "from" and "Sendai".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. ' 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. ' 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1, 2, 4-6, 8, 9, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 USC 103 as being unpatentable over either Fernandez (US Pat No. 5,820,879) or Dunn (WO 97/04747).

The claims are drawn to a slow-release composition comprising nanospheres that encapsulate a physiologically active substance and which are encapsulated in liposomes having fusogenic capability, wherein the nanospheres have a particle size of 10 – 600 nm, and to a delivery method of employing the composition. Fernandez and Dunn teaches the same throughout the disclosure, *e.g.,* abstract, column 2, lines 24-43, column 13, lines 26-42, column 20 through column 21, column 33 (Fernandez); pages 3-4, page 5, pages 6-7, example 3, and page 19 (Dunn). Since both Fernandez and Dunn teaches that liposomes act to fuse or contact the cell membrane of a target cell and to piggyback its contents (nanoparticles encapsulating a biologically active substance) into the cell, the liposomes of the references exhibit a fusogenic capability. To the extent that the claims embrace an addition to numerous known fusogenic substances to the surface of the liposomes of the references so as to increase their bioadhesiveness or fusogenic capability, it would have been obvious to one of ordinary skill in the art that addition(s) of well-know bioadhesive adjuvants and/or fusogenic substances, as evidenced by the teaching of the exemplified Dunn and/or art cited in the as-filed specification (p. 2 bridging p. 3) are conventional, and thus, one would have been motivated to employ such

adjuvants and/or substances to make surface-modified liposomes thereby increasing the efficiency of liposomes as carriers to transport biologically active substances across the extracellular membrane of target cell.

Thus, the claimed invention is anticipated by the cited references, or in the alternative, is *prima facie* obvious, over the prior art as a whole.

Claims 1-3, 7, 10, 12 are rejected under 35 USC 103 as being obvious over Fernandez or Dunn, taken with Rozenberg (US 20002/0064520).

The rejection over the base claims is applied here as indicated above. To the extent that the Fernandez and Dunn references are silent over an addition or incorporation of a Sendal virus to the encapsulated liposomes so as to increase their fusogenic capability, and to the extent that the claims embrace such addition or incorporation, the state of the prior art exemplified by Rozenberg teaches that an application of a Sendai virus as a component of fusogenic liposomes in gene delivery is well-recognized in the prior art, and that such application was used to increase a functional retargeting and fusogenic capability of liposomal carrier to deliver its encapsulated biologically active substances to a desired host cell (page 9, par. 0092).

It would have been obvious for one of ordinary skill in the art to add or incorporate a Sendal virus to the encapsulated liposomes of Fernandez or Dunn so as to increase their fusogenic capability. One would have been motivated to do so because the state of the prior art exemplified by Rozenberg teaches that an application of a Sendai virus as a component of fusogenic liposomes in gene delivery is well-recognized in the prior art, and that such application was used to increase a functional retargeting and fusogenic capability of liposomal carrier to deliver its encapsulated biologically active substances to a desired host cell.

Thus, the claimed invention as a whole was *prima facie* obvious.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds* may be reached at **(703) 305-4051.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

DAVE T. NGUYEN
PRIMARY EXAMINER